

## **REMARKS**

### **Status of the Claims**

Claims 2, 5-10, 12-25, 27-30, 32 and 34-39 were pending.

Claims 2, 5-10, 12-25, 27-30, 32 and 34-39 were rejected in the Office Action of March 8, 2006.

By way of this amendment, claims 2, 5-8, 13, 17-25, 27-30, 32, and 35-39 have been canceled without prejudice to their presentation in another application; and claim 9 has been amended.

**Because the amendments to the claims remove issues for appeal (*i.e.*, enablement, anticipation, and obviousness rejections), Applicants respectfully request that they be entered into the record. See, M.P.E.P. §714.12.**

Upon entry of this amendment, claims 9, 10, 14-16, and 34 will remain pending.

### **Summary of the Invention**

Claim 9 has been amended to recite that the DNA molecule is operably linked to a secretion signal, and that the promoter is selected from the group consisting of a M-CSFR promoter, a CD156 promoter, a catalase promoter, a p73 promoter, and an FcγRI promoter.

Support for the amendments is found throughout the specification and claims as originally filed. No new matter has been added.

### **Objections to the Claims**

Claims 2 and 32 stand objected to for being of improper form for failing to further limit the subject matter of a previous claim. Solely to advance prosecution of the present application, however, claims 2 and 32 have been canceled without prejudice to their presentation in another application. Accordingly, the objection is now rendered moot.

**Double Patenting**

Claim 32 stands objected to as being a substantial duplicate of claim 5. Solely to advance prosecution of the present application, however, claim 32 has been canceled without prejudice to its presentation in another application. Accordingly, the objection is now rendered moot.

**Rejections under 35 U.S.C. § 112, first paragraph – Enablement**

The enablement rejection as set forth in the Office Action is provided in two parts. In the first part, claims 2, 5-10, 13-25, 27-30, 32, and 34-39 stand rejected under 35 U.S.C. §112, first paragraph, because while enabling specific embodiments, it is asserted that the specification does not enable the claimed invention for any macrophage-specific promoter derived from a human gene, or the delivery of proteins to the lymphnode where the protein is not linked to a secretion signal. (Office Action, page 6). Applicants traverse the rejection and respectfully request reconsideration thereof in view of the amended claims.

Although Applicants disagree with the reasoning set forth in the Office Action for the reasons of record, solely to advance prosecution of the present application, the claims have been amended to reflect that which the Office Action recognizes as being enabled. For example, claim 9 has been amended to recite that the DNA molecule is operably linked to a secretion signal, a promoter and a polyadenylation signal that are functional in a macrophage cell, and that the promoter is selected from the group consisting of a M-CSFR promoter, a CD156 promoter, a catalase promoter, a p73 promoter, and an Fc $\gamma$ RI promoter.

In the second part of the enablement rejection, claims 18-25 and 27-30 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. The Office Action continues to assert that claims reciting a method of inducing an immune response, a method of modulating an individual's immune system, and a method of eliminating cells in a lymphnode are not enabled due to hurdles present in gene therapy. Although Applicants disagree with the reasoning set forth in the Office Action for the reasons of record (and maintain that the Examiner continues to erroneously apply gene therapy references), solely to advance prosecution of the present application, claims 18-25 and 27-30 have been canceled without

prejudice to their presentation in another application. Accordingly, the second part of the enablement rejection is now rendered moot.

In view of the foregoing, Applicants respectfully assert that the claims as pending are enabled and the that rejection of the pending claims under 35 U.S.C. §112, first paragraph, as not complying with the enablement requirement should be withdrawn.

### **Rejections under 35 U.S.C. §102**

Claim 29 stands rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent Application No. 20004/0063652. Although Applicants disagree with the reasoning set forth in the Office Action for the reasons of record, solely to advance prosecution of the present application, claim 29 has been canceled without prejudice to its presentation in another application. Accordingly, the anticipation rejection is now rendered moot.

### **Rejections under 35 U.S.C. §103**

Claims 1, 5, 7, 8, 17, 32, and 35 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent Application No. 20004/0063652 and Ross et al., 1998, J. Biol. Chem., 273(12):6662-69. Although Applicants disagree with the reasoning set forth in the Office Action for the reasons of record, solely to advance prosecution of the present application, claims 1, 5, 7, 8, 17, 32, and 35 have been canceled without prejudice to their presentation in another application. Accordingly, the obviousness rejection is now rendered moot.

Claim 6 stands rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent Application No. 20004/0063652 and Kotaoka et al., 1997, J. Biol. Chem., 272(29):18209-15 and further in view of U.S. Patent No. 5,763,416. Although Applicants disagree with the reasoning set forth in the Office Action for the reasons of record, solely to advance prosecution of the present application, claim 6 has been canceled without prejudice to its presentation in another application. Accordingly, the obviousness rejection is now rendered moot.

### **Other Matters**

The Office Action asserts that no prior art that indicates targeting of specific lymphnodes local to a site of administration for delivery of proteins by macrophages could be found (see "Note to Applicant", page 14). Applicants thank the Examiner for recognizing the novelty of claims 9, 10, 14-16 and 34. The Office Action, however, asserts that U.S. Patent No. 5,783,567 teaches that macrophages drain into lymph nodes (referring to column 8, paragraph 3), and that such aspect is considered inherent in Jolly. Upon careful review of column 8, paragraph 3 of U.S. Patent No. 5,783,567, however, no such teaching is found. The only passage in this section referring to lymph nodes is:

Alternatively, one can target, via subcutaneous injection, take-up  
by the phagocytic cells of the draining lymph nodes.

This passage does not teach or suggest that macrophages drain into lymph nodes. Rather, this passage, at most, reports that the microparticles can be taken up by phagocytic cells of the draining lymph nodes when the microparticles are injected subcutaneously. There is no indication whether the phagocytic cells subcutaneously take up the microparticles and then deliver them to the lymph nodes, or whether the microparticles reach the lymph nodes where they are simply taken up by phagocytic cells within the lymph nodes.

Regardless of the teachings in U.S. Patent No. 5,783,567, none of the prior art of record (including U.S. Patent No. 5,783,567), teach or suggest identifying a lymph node to which a protein is to be delivered, locating a site on an individual's body that is proximal to the lymph node, and administering to the individual at the site.

Further, because the "Note to Applicants" has not been fully explained or described, Applicants are unable to respond to a future rejection which has not yet been made. The Office is respectfully reminded that all rejections should be made and that examination is not to be done in a piecemeal manner. If such a new ground of rejection is included in a future Office Action (including an Advisory Action), that office action should not be final.

**Conclusion**

Claims 9, 10, 14-16 and 34 are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 665-6914 to clarify any unresolved issues raised by this response.

Respectfully submitted,

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